



**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-17-0199; Docket No. CDC-2017-0058]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the *Import Permit Applications* information collection project.

**DATES:** Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2017-0058 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comments should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the

Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden is the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of

collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel to respond to a collection of information, search data sources, and complete and review the collection of information; and to transmit or otherwise disclose the information.

#### Proposed Project

Importation of Etiologic Agents (42 CFR 71.54) (OMB Control No. 0920-0199, exp. 12/31/2019) - Revision - Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, authorizes the Secretary of Health and Human Services to make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F - Importations - contains provisions for the importation of infectious biological agents, infectious

substances, and vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC.

The Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form is used by laboratory facilities, such as those operated by government agencies, universities, and research institutions to request a permit for the importation of biological agents, infectious substances, or vectors of human disease. This form currently requests applicant and sender contact information; description of material for importation; facility isolation and containment information; and personnel qualifications. CDC plans to revise this application to:

- (1) Based on processing applications, remove questions that duplicative or not required to process the import permit request such as CDC plans to revise this application to request information on where the imported material will be stored at the recipient facility and who would be responsible for this location and revise the format for the form to ease of user to complete the form.
- (2) Request information the biosafety officer's contact information for the permittee to provide biosafety information in case the permittee is unavailable.

These additional data requests will not affect the burden hours.

In addition, CDC proposes to revise the Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form to verify that the recipient for subsequent transfers has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use. CDC believes that it will take the applicant additional 10 minutes to complete this section for subsequent transfers. Estimates of burden for the additional questions survey are based on information obtained from the CDC import permit database on the number of permits issued for 2016 for subsequent transfers, which is 380 permits.

The Application for Permit to Import or Transport Live Bats form is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation, and any subsequent distribution after importation, of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation and containment information. CDC plans to revise this application

to add a question about what personal protective measures will be used. This additional data request will not affect the burden hours.

Estimates of burden for the survey are based on information obtained from the CDC import permit database on the number of permits issued on annual basis since 2010. The total estimated burden for the one-time data collection is 1592.

There are no costs to respondents except their time.

#### Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States	2380	1	30/60	1190
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States Guidance	2380	1	10/60	397

Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats	10	1	20/60	3
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats	10	1	10/60	2
Total					1592

**Leroy A. Richardson,**

*Chief,*

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*Office of the Director,*

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